In the Supreme Court of the United States

OCTOBER TERM, 1967

No. 1374

AN ARTICLE OF DEVICE . . . DIAPULSE MANUFACTURING CORPORATION OF AMERICA, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. 20-26) is reported at 389 F.2d 612.

JURISDICTION

The judgment of the court of appeals was entered on January 30, 1968. The petition for a writ of certiorari was filed on April 29, 1968. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTES, REGULATION, AND RULE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended (21 U.S.C. 301, *et seq.*), provides in pertinent part:

Section 201(m) (21 U.S.C. 321(m)):

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Section 201(n) (21 U.S.C. 321(n)):

> If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations * * *.

Section 304(a)(1) (21 U.S.C. 334(a)(1) (Supp. II)):

> Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *.

Section 502(a) (21 U.S.C. 352(a)):

> A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

21 C.F.R. 1.3 provides:

> The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Rule 49(b), F. R. Civ. P. provides:

> *General Verdict Accompanied by Answer to Interrogatories.* The court may submit to the jury, together with appropriate forms for a general verdict, written interrogatories upon one or more issues of fact the decision of which is necessary to a verdict. The court shall give such explanation or instruction as may be necessary to enable the jury both to make answers to the interrogatories and to render a general verdict, and the court shall direct the jury both to make written answers and to render a general verdict. When the general verdict and the answers are harmonious, the appropriate judgment upon the verdict and answers shall be entered pursuant to Rule 58. * * *

QUESTIONS PRESENTED

1. Whether issues relating to the effectiveness of the device to treat certain conditions were improperly submitted to the jury, because the government's expert witnesses testified that there was some difference of medical opinion on these issues.

2. Whether the trial court properly instructed the jury that labeling may be misleading if it fails to disclose a material difference of scientific opinion with respect to the truth of its representations.

3. Whether the trial court correctly held, as a matter of law, that the promotional materials seized with the device constituted "labeling."

4. Whether the trial court abused its discretion in the method by which it requested the jury to answer special interrogatories as to the specific claims which it found to be false or misleading.

STATEMENT

On December 17, 1965, the United States filed a Libel of Information in the Northern District of Georgia for condemnation of a "Diapulse" device, alleging that the device (a diathermy or heating unit), shipped in interstate commerce, was misbranded within the meaning of Section 502(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(a). The information also alleged that the device was in the possession of an Atlanta chiropractor and that its labeling (several pieces of printed and graphic matter provided by the manufacturer) contained false and misleading representations that the device was adequate and effective for treating some 121 different diseases and ailments.

After seizure of the device and the printed and graphic materials, Diapulse Manufacturing Corporation of America intervened as claimant, and on its motion the action was removed to the District of Connecticut pursuant to Section 304(a)(1) of the Act, 21

U.S.C. 334(a)(1) (Supp. 1967). On March 17, 1967, a jury returned a verdict that the device was misbranded and answers to special interrogatories setting out 49 respects in which the labeling was found false or misleading (Pet. App. 29-32). Judgment of condemnation was entered but was subsequently modified, pursuant to Section 304(d) of the Act, 21 U.S.C. 334(d) (Supp. 1967), to permit the claimant to relabel the device. The court of appeals affirmed (Pet. App. 20-26).

ARGUMENT

1. Petitioner contends that because government witnesses acknowledged that there was some difference of medical opinion with respect to the issues of effectiveness raised in the libel, these issues should not have been submitted to the jury (Pet. 9-10). As the district court pointed out, however, in ruling on a motion for a new trial (269 F. Supp. 162, 165):

> * * * Witness after witness testified to the existence of bona fide analytic methods by which scientists can determine effectiveness. Laboratory tests were conducted. Control groups were employed. Just as in *Seven Jugs*, "[t]hese tests were recognized by outstanding men of science as constituting conclusive evidence by recognized scientific standards that the remedies were wholly ineffective." 53 F. Supp. 759. * * *

Under petitioner's theory—that the mere fact of a difference of medical opinion renders the issue of misbranding non-justiciable—no libel could be maintained if a claimant could produce one doctor who was

willing to support the claims made. That is clearly an untenable position. Since the government's expert witnesses based their opinions on scientific standards and methods capable of testing the effectiveness of the device, the evidence presented questions of fact which were properly submitted to the jury. See *United States* v. *47 Bottles, More or Less, Etc.*, 320 F.2d 564, 571 (C.A. 3). The evidence amply supports the jury's finding that the device was misbranded.

2. Petitioner contends that the court erred in instructing the jury that labeling may be misleading if it fails to disclose a difference of medical opinion with respect to the truth of its representations. The court emphasized that this issue presents a question whether there were "any significant studies unfavorable to Diapulse" that the company knew or should have known about and did not disclose (R. 2727). While not challenging the instruction as a correct statement of the law, petitioner argues that the absence of a specific allegation in the libel or interrogatories in this respect deprived it of adequate notice (Pet. 5-6).

By operation of the statute and regulations (see pp. 2-3, *supra*), however, the allegation of false and misleading labeling necessarily encompassed this issue. Under the statutory scheme, a libel offers clear warning that the honesty of the labeling is fully to be tested. It is not necessary that the libel spell out in detail every half-truth which may constitute misleading labeling.

The record indicates, moreover, that petitioner was fully aware of the issues comprehended by the allega-

tion of misleading labeling. Counsel argued to the jury at the outset of trial that petitioner had looked to "the work of many scientists" and had "said so when the results did not show up well from a particular scientist." Counsel promised to present "a picture of a company who has taken a machine and given the facts as presented by the physicians to the physicians;" a company that had taken pains to present "a fair, honest, complete presentation of the facts, nothing distorted, not buried, not hidden" (R. 10-11).

3. The written and graphic material which constituted the false and misleading labeling charged in the libel was admitted into evidence without objection (R. 58), and after the government rested, petitioner moved for a directed verdict solely on the ground that the labeling did not make the representations alleged in the libel (R. 1012-1015). Only at the close of all the evidence did petitioner argue that the materials were not labeling (R. 2683).

Contrary to petitioner's contention, the holding of the courts below that the literature constituted "labeling" as a matter of law is not in conflict with this Court's decisions in *Kordel* v. *United States*, 335 U.S. 345, and *United States* v. *Urbuteit*, 336 U.S. 804. Petitioner admitted in its answers to interrogatories and at trial that it had distributed the promotional materials and that they were seized, together with the device, from the premises of a chiropractor to whom it had sold the device. The materials have an obvious "textual relationship" to the device (*Kordel* v. *United States*, *supra*, 335 U.S. at 350), and their obvious and unique purpose was to promote the pur-

chase and use of the device by chiropractors. In these circumstances, where the literature evidently had accomplished its purpose, the fact that it was "used" with the device was established. Compare *United States* v. *47 Bottles, More or Less, Etc.*, *supra*, 320 F.2d at 568-569.

4. The trial court instructed the jury to return a general verdict, either for the government or for the device, and if its verdict was for the government, to indicate on a separate form (Pet. App. 29-32) which of the 121 claims in the labeling it found to be false or misleading. The jury returned a general verdict in favor of the government and found the labeling false or misleading in 49 particulars. Petitioner's objection to this procedure is based on the court's instruction that the jury should specify its findings only as to those claims which it thought were central to the government's case, and that it was not required to answer the interrogatories for all of the 121 claims listed. However, the use of special interrogatories, as well as their form and content, is within the discretion of the trial court. Rule 49(b), Fed. R. Crim. P.; see 5 Moore, *Federal Practice* § 49.04 (2d ed. 1967). The court adopted the interrogatory procedure used here to insure that the jury would rivet its attention upon and actually resolve claims individually, without requiring it to deliberate until the 121 claims were exhausted. This plainly was not an abuse of discretion. As the court of appeals held (Pet. 23), the function of the action was to protect the public from the misbranded device and not to advise the manufacturer of the precise defects in the labeling. The fact

that the court's judgment afforded claimant an opportunity to correct its labeling does not require a different form of verdict.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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